

REMARKS

In response to the Office Action mailed October 5, 2007, claims 2-4, 6, 9-11, 14, 16, and 46-58 have been canceled without prejudice, claims 1, 5, 25, and 26 have been amended and new claims 59-73 have been added. Accordingly, claims 1, 5, 7, 8, 21-31, and 59-73 are currently pending.

Support for the present amendments may be found throughout the original disclosure, for example, the amendments to claims 1 and 5 may be found throughout the specification, e.g., in paragraph [0111], and the drawings, e.g., in FIG. 4. Support for the new claims may be found in the original claims, in the specification, e.g., in paragraphs [0066], [0115], [0118]-[0120], and in the drawings, e.g., in FIGS. 5, 7-9, and 17. No new matter has been introduced.

In the Office Action, claims 1, 2, 6, 9, 11, 14, 16, 25-31, 48, and 52-58 were rejected under 35 U.S.C. § 112, second paragraph, as indefinite. In addition, claims 1-6, 9, 14, and 16 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,203,218 (“the Dal Pont reference”), claims 46-58 were rejected either under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,453,661 (“the Genyk et al. reference”), and claims 7, 8, 10, and 11 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Dal Pont reference. Finally, claims 47-58 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,162,233.

Because neither of the cited references, either alone or in combination, discloses, teaches, or suggests the subject matter of the present claims, the rejections should be withdrawn.

Turning first to the judicially created doctrine of double patenting rejections, Applicants submit herewith a Terminal Disclaimer disclaiming the terminal part of any patent granted on the

present application that would extend beyond the expiration date of U.S. Patent Nos. 5,972,004 and 6,162,233. Therefore, the double patenting rejections should be withdrawn.

With respect to the § 112, second paragraph, rejections, although Applicants believe the original language was definite, claims 1, 25, and 26 have been amended to more particularly recite the claimed fastener and method. For example, claim 1 has been amended to recite that the leg is “configured to be cut to a formed length dimension measured between said base and an end, with the end located between the pointed end and said base such that the unformed length is greater than the formed length.” Claim 25 has been amended to replace “forming the fastener” with “cutting the fastener to form an end between the base and the pointed end.” Finally, claim 26 has been amended to delete the language related to the unformed and formed configurations, since the configuration of the fastener is defined by the steps of the claimed method. Since claims 1, 2, 6, 9, 11, 14, 16, 48, and 52-58 have been canceled without prejudice, the rejections of these claims is now moot. Accordingly, Applicants request that the § 112, second paragraph, rejections be withdrawn.

Turning to the § 102(b) rejections, the Dal Pont reference discloses a U-shaped implant that includes a bight portion 1 and two approximately parallel arms 2. Col. 1, lines 62-68. The bight portion 1 is flattened and provided with a sharp straight external transverse edge 1'. Col. 1, lines 64-66. During use, the sharpened edge 1' is inserted into a fissure in a cortical plate, and the implant is hammered into the bone. Col. 2, lines 16-24. Artificial teeth may then be applied to the (possibly cut and/or bent) arms 2a. Col. 2, lines 28-30.

Turning to the present claims, claim 1 recites a fastener for use in surgery that includes a body having a base and a leg extending from said base; said body having a width dimension; said

leg having a pointed end, an unformed length dimension measured from said base to said pointed end, the leg configured to be cut to a formed length dimension measured between said base and an end, with the end located between the pointed end and said base such that the unformed length is greater than the formed length; and a pledget on the body adjacent the base.

First, the Dal Pont reference fails to disclose, teach, or suggest anything about a pledget, as claimed. A pledget is applied to a fastener to provide extra contact area, e.g., to help support tissue through which a fastener is delivered to prevent the fastener from tearing or otherwise damaging the tissue, as can be seen in FIGS. 4 and 5 of the present application. In direct contrast, the Dal Pont implant has a sharpened edge that is intended to facilitate insertion of the implant into a fissure in bone. A person of ordinary skill would appreciate that applying a pledget to the Dal Pont implant would undermine its ability to be inserted into a fissure in bone.

Second, the Dal Pont reference does not disclose, teach, or suggest a fastener that includes a body having a base and a leg having a pointed end, as claimed. The arms of the Dal Pont implant do not include a pointed end, because the arms are not delivered through tissue; instead, the sharpened edge of the bight portion 1 is inserted into bone. Accordingly, for these reasons, claim 1 is neither anticipated by nor otherwise obvious over the Dal Pont reference.

For similar reasons, claim 5 and its dependent claims are also neither anticipated by nor otherwise obvious over the Dal Pont reference.

Turning to new claim 59, a method is recited for placing a prosthetic device during surgery that includes placing a plurality of long wire fasteners through tissue at a surgical site, the fasteners comprising legs that extend outside the patient; guiding a sewing cuff down the legs to

place the sewing cuff at the surgical site; and guiding a prosthetic device down the legs into place next to the sewing cuff.


Neither of the cited reference discloses, teaches, or suggests anything about guiding a sewing cuff or prosthetic device down legs of long wire fasteners, as claimed. Accordingly, claim 59 and its dependent claims are neither anticipated by nor otherwise obvious over the cited references.

Finally, for similar reasons, new claim 67 is also neither anticipated by nor otherwise obvious over the cited references. Further, claim 67 also recites cutting portions of the legs adjacent the prosthetic device to form the fasteners into anchors, and forming the remaining portions of the legs to secure the prosthetic device at the annulus, which is not disclosed, taught, or suggested by the cited references.

In view of the foregoing, it is submitted that the claims now presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

Respectfully submitted,

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